AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) An isolated anti ~~Anti~~-human tenascin monoclonal antibody or proteolytic fragments thereof, ~~preferably murine~~, comprising ~~whose~~ a light chain variable region of SEQ ID NO:2 ~~and~~ a heavy chain variable region ~~sequences are SEQ ID 1 and~~ of SEQ ID NO:4 ~~2, respectively~~, ~~its proteolytic fragments thereof~~, wherein said light chain variable region and said heavy chain variable region are capable of binding to an antigenic epitope within the $A_{(1-4)}$-D region of human tenascin, ~~its recombinant derivatives, its conjugates and similar functional analogues capable of binding to an antigenic epitope with the $A_{(1-4)}$-D region of human tenascin~~.

2. (Currently Amended) Fragments of the antibody according to claim 1, ~~optionally~~ further containing additional markers and diagnostic agents.

3-7. (Cancelled).

8. (Currently Amended) The antibody or the proteolytic fragments thereof ~~Biotinylated antibody~~ according to claim 1, wherein said antibody or said proteolytic fragments thereof are biotinylated ~~or biotinylated fragments or biotinylated derivatives as defined above~~.

9. (Previously Presented) DNA encoding the antibody according to claim 1 or fragments as defined above.

10. (Original) A vector containing the DNA according to claim 9.

11. (Original) Host cell containing the vector according to claim 10.

12. (Currently Amended) ~~Protein~~ An isolated antibody or fragments thereof coded for by the nucleotide sequences SEQ ID NO:1 and SEQ ID NO:3 ~~2 or its fragments~~.

13. (Original) DNA encoding the protein or its fragments according to claim 12.

14. (Original) Specific CDRs (Complementary Determining Regions) of the antibody according to claim 1 and proteins containing said CDRs.

15. (Currently Amended) Hybridoma producing the antibody according to claim 1, deposited at the Centro di Biotecnologie Avanzate, Largo Rossana Benzi 10 Genoa – Italy on 12 November 2003 in accordance with the provisions of the Budapest Treaty, ~~under deposit~~ with the accession number PD03003.

16. (Currently Amended) Process for the preparation of the antibody according to claim 1 comprising

a) ~~immunization of~~ immunizing an animal with the $A_{(1-4)}$-D fragment of human tenascin;

b) ~~fusion of~~ fusing somatic spleen cells of said animal with myeloma cells not producing immunoglobulins;

c) ~~selection of~~ selecting the monoclonal antibody.

17. (Previously Presented) Use of the antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or of its fragments, optionally biotinylated, or of its biotinylated derivatives for the preparation of a pharmaceutical product useful for the treatment or diagnosis of a disease characterized by expression of tenascin.

18. (Original) Use according to claim 17, in which said disease is a tumor.

19. (Original) Use according to claim 18, in which said tumor is selected from the group consisting of glioma, cancer of the breast, carcinoma of the lung, fibrosarcoma and squamous-cell carcinoma.

20. (Previously Presented) Use of the antibody or its proteolytic fragments or its

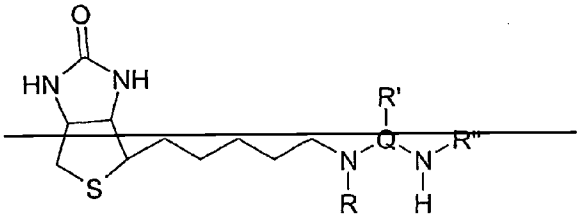
recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or of its fragments, optionally biotinylated, or of its biotinylated derivatives for the preparation of a pharmaceutical product useful for the two-stage perioperative therapy of solid tumors.

21. (Currently Amended) Pharmaceutical or diagnostic compositions containing an antibody or ~~its~~ proteolytic fragments thereof ~~or its recombinant derivatives or its conjugates or analogues~~ according to claim 1, ~~optionally biotinylated, or its fragments, optionally biotinylated, or its biotinylated derivatives in mixtures~~ with at least one pharmaceutically acceptable vehicle ~~and/~~or excipient.

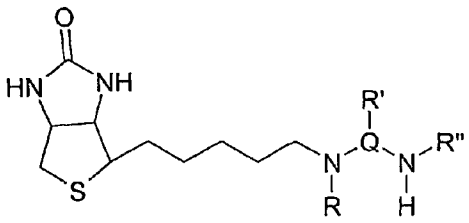
22. (Currently Amended) Kit for systemic radioimmunotherapy, ~~particularly three-step pre-targeting radioimmunotherapy~~, consisting of 5 vials~~:~~ wherein vial 1~~containing an~~ contains the antibody or ~~its~~ the proteolytic fragments thereof ~~or its recombinant derivatives or its conjugates or analogues~~ according to claim 1;~~,~~ ~~optionally biotinylated, or fragments optionally biotinylated or biotinylated derivatives~~;vial 2 ~~containing~~ contains avidin;~~,~~ vial 3 contains ~~containing~~ streptavidin; vial 4 contains c~~ontaining~~ biotinylated human albumin; and vial 5 contains ~~containing~~ biotin DOTA.

23. (Currently Amended) Kit for locoregional radioimmunotherapy consisting of 3 vials; wherein vial 1 contains ~~containing an~~ the antibody or ~~its~~ the proteolytic fragments thereof ~~or its recombinant derivatives or its conjugates or analogues~~ according to claim 1, ~~optionally biotinylated, or its fragments, optionally biotinylated, or biotinylated derivatives~~; vial 2 contains ~~containing~~ avidin; and vial 3 contains ~~containing~~ biotin DOTA.

24. (Currently Amended) Kit according to claim 22 wherein ~~in which~~ said biotin DOTA

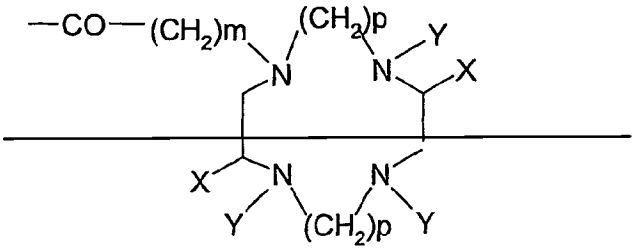


in vial 5 ~~or vial 2, respectively,~~ is the formula (I) compound

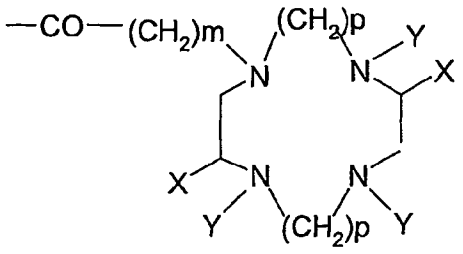


(I)

in which Q is a $-(CH_2)n-$ group, where n is a whole number from 4 to 12, in which case R' is not present, or Q is selected from the group consisting of $-(CH_2)_a-CH(R')_b-(CH_2)_b-$, where a and b are independently whole numbers from 0 to n, wherein n is as defined above, R' is as defined here below, or Q is cyclohexyl, phenyl, in which case R' is a substituted on the cyclohexyl or phenyl ring;



R is hydrogen or $-\Lambda$ where $-\Lambda$ is a formula (II) macrocycle



(II)

where the various Y's which may be the same or different, are selected from the group consisting of hydrogen, straight or branched C_1-C_4 alkyl, -$(CH_2)_m$-COOH, where m is a whole number from 1 to 3, X is hydrogen, or the group –CH_2-U, where U is selected from the group consisting or methyl, ethyl, and p-aminophenyl, or X is the group –$(CHW)_o$-Z, where o is a whole number from 1 to 5, W is hydrogen, methyl or ethyl, Z is a 5- or 6- member heterocyclic group containing one or more heteroatoms selected from O, N-R_1, where R_1 is hydrogen or straight or branched C_1-C_4 alkyl, and S; or Z is selected from the group consisting of –NH_2, -NH-C(=NH)-NH_2, or –S-R_2, where R_2 is straight or branched C_1-C_4 alkyl;

p is the number 2 or 3;

R' is selected from the group consisting of hydrogen, straight or branched C_1-C_4 alkyl, -$(CH_2)_q$-T, in which T is selected from the group consisting of –S-CH_3, -OH, -COOH, and q is the number 1 or 2;

R" has the same meanings as R', upon the following conditions: if R is –Λ, R" is hydrogen, if R is hydrogen, R" is –Λ, or R and R" are, respectively –$(CH_2)_r$-Λ (for R), where r is a whole number from 4 to 12, and –Λ (for R'), Q being a -$(CH_2)_n$- group, where n is a whole number from 4 to 12.

25. (Previously Presented) Kit according to claim 22, in which vial 3 contains an avidin dimer in which two avidin molecules are bound via the $-NH_2$ groups by means of suberate.

26. (Previously Presented) Kit according to claim 22, in which said vial 3 contains an avidin dimer in which two avidin molecules are bound via the –COOH groups by means of polyethylene glycol with a molecular weight of 3,400.

27. (Currently Amended) Kit according to claim 22, in which the antibody or ~~its~~ the proteolytic fragments thereof ~~or its recombinant derivatives or its conjugates or analogues~~, ~~optionally biotinylated, or its fragments optionally biotinylated, or its biotinylated derivatives,~~ are combined with other anti-tenascin antibodies, ~~preferably targeting the EGF-like region of the protein~~.

28. (Currently Amended) Kit according to claim 22, ~~in which~~ wherein the antibody or the ~~its~~ proteolytic fragments thereof, ~~or its recombinant derivatives or its conjugates or analogues, optionally biotinylated, or its fragments optionally biotinylated, or its biotinylated derivatives~~ are combined with other tumor-specific antibodies.

29. (Previously Presented) Use of the antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments optionally biotinylated, or its biotinylated derivatives in the preparation of compositions useful in the tumor immunolocalization procedure.

30. (Currently Amended) Container, ~~preferably in the form of a vial, suitable for injection~~, containing the ~~an~~ antibody or the ~~its~~ proteolytic fragments thereof ~~or its recombinant derivatives or its conjugates or analogues~~ according to claim 1, ~~optionally biotinylated, and/or radiolabelled or its fragments, optionally biotinylated, or its biotinylated derivatives~~.

31. (Previously Presented) Tumor imaging method including the administration of an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments, optionally biotinylated, or its biotinylated derivatives to a person suffering from or suspected of suffering from a tumor, and the detection of said tumor.

32. (Original) Method according to claim 31, in which the antibody or its proteolytic fragments or recombinant derivatives or conjugates of analogues are radiolabelled.

33. (Previously Presented) Combination comprising ~~containing~~ the antibody or its the proteolytic fragments thereof ~~or recombinant derivatives or conjugates or analogues~~ according to claim 1, ~~or fragments or derivatives~~ and a second tenascin-specific antibody.

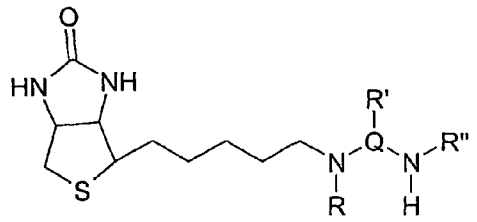
34. (Original) Use of the combination according to claim 33 in a sandwich-type *in-vitro* ELISA assay, in conditions in which said second antibody binds to a second antigenic epitope, for the purposes of determining circulating tenascin levels, particularly levels of the isoforms containing the $A_{(1-4)}$-D region.

35. (New) An isolated murine anti-human tenascin monoclonal antibody or proteolytic fragments thereof comprising a light chain variable region of SEQ ID NO:2 and a heavy chain variable region of SEQ ID NO:4, wherein said light chain variable region and said heavy chain variable region are capable of binding to an antigenic epitope within the $A_{(1-4)}$-D region of human tenascin.

36. (New) Recombinant derivative of the antibody according to claim 35 comprising a human constant region.

37. (New) Kit according to claim 23 wherein in which said biotin DOTA

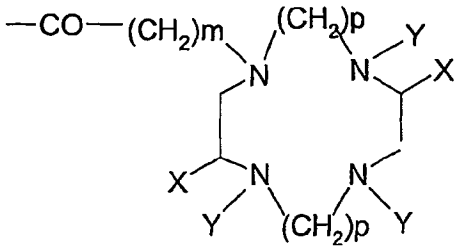
in vial 2 is the formula (I) compound



(I)

in which Q is a $-(CH_2)n-$ group, where n is a whole number from 4 to 12, in which case R' is not present, or Q is selected from the group consisting of $-(CH_2)_a-CH(R')_b-(CH_2)_b-$, where a and b are independently whole numbers from 0 to n, wherein n is as defined above, R' is as defined here below, or Q is cyclohexyl, phenyl, in which case R' is a substituted on the cyclohexyl or phenyl ring;

R is hydrogen or –Λ where –Λ is a formula (II) macrocycle



(II)

where the various Y's which may be the same or different, are selected from the group consisting of hydrogen, straight or branched C_1-C_4 alkyl, $-(CH_2)_m-COOH$, where m is a whole number from 1 to 3, X is hydrogen, or the group $-CH_2-U$, where U is selected from the group consisting or methyl, ethyl, and p-aminophenyl, or X is the group $-(CHW)_o-Z$, where o is a whole number from 1 to 5, W is hydrogen, methyl or ethyl, Z is a 5- or 6- member heterocyclic group containing one or more heteroatoms selected from O, N-R_1, where R_1 is hydrogen or straight or

branched C_1-C_4 alkyl, and S; or Z is selected from the group consisting of $–NH_2$, -NH-C(=NH)-NH_2, or $–S-R_2$, where R_2 is straight or branched C_1-C_4 alkyl;

p is the number 2 or 3;

R' is selected from the group consisting of hydrogen, straight or branched C_1-C_4 alkyl, $-(CH_2)_q$-T, in which T is selected from the group consisting of $–S-CH_3$, -OH, -COOH, and q is the number 1 or 2;

R" has the same meanings as R', upon the following conditions: if R is –Λ, R" is hydrogen, if R is hydrogen, R" is –Λ, or R and R" are, respectively $–(CH_2)_r$-Λ (for R), where r is a whole number from 4 to 12, and –Λ (for R'), Q being a $-(CH_2)_n$- group, where n is a whole number from 4 to 12.